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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|------------------------|---------------------|
| 10/675,459 | 09/30/2003 | Richard L. Mueller JR. | ACU-128 | 5616 |
| 7590 OLSON & HIERL, LTD. 36th Floor 20 North Wacker Drive Chicago, IL 60606 | | | EXAMINER [REDACTED] | FOREMAN, JONATHAN M |
| ART UNIT 3736 | | PAPER NUMBER | | |
| MAIL DATE 11/16/2007 | | DELIVERY MODE PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|---------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/675,459 | MUELLER, RICHARD L. |
| | Examiner | Art Unit |
| | Jonathan ML Foreman | 3736 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 June 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,10,23,32,45 and 54 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,10,23,32,45 and 54 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. As a result of the Panel Decision from Pre-Appeal Brief Review mailed 9/5/07, the finality of the action mailed 12/21/06 is withdrawn.

Claim Objections

2. Claims 10 and 54 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 states, "the distal end portion of the cutter tube including at least one cutting edge". Claim 10 fails to further limit the subject matter of claim 1. Claim 45 states, "the cutter distal end portion having a tubular configuration and including a cutting edge". Claim 54 fails to further limit the subject matter of claim 45.
3. Claim 45 is objected to because of the following informalities: line 13 states "being received inserted within...". Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 45 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,505,210 to Clement.

In regard to claims 45 and 54, Clement discloses a biopsy device (Figure 1 – 4) suitable for collection of a tissue sample from a biopsy site in a body lumen, the biopsy device comprising an introducer assembly (20) having an introducer distal end portion (24), a cutter assembly (50) within

the introducer assembly and having a cutter distal end portion, and an endoscope (38) within the cutter assembly and having a fiber optic bundle distal end portion; a working end portion of the biopsy device comprising the introducer distal end portion, the cutter distal end portion, and the fiber optic bundle distal end portion; the introducer distal end portion having a tubular configuration and defining at least one side aperture (30); the cutter distal end portion having a tubular configuration and including a cutting edge (52); the cutter distal end portion being slidably received within the introducer distal end portion and the fiber optic bundle distal end portion being sized to be received within the cutter distal end portion, and the cutter distal end portion coacting with the introducer distal end portion to cut the tissue sample (Col. 5, lines 45 – 49).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1 and 10, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,505,210 to Clement in view of U.S. Patent No. 5,285,795 to Ryan et al.

In regard to claims 1 and 10, Clement discloses a biopsy device (Figures 1 – 4) suitable for collection of a tissue sample from a biopsy site in a body lumen, the biopsy device comprising: an introducer assembly (20) comprising a hollow sheath having a distal end portion (24) and a proximal end portion, and the distal end portion of the introducer sheath defining at least one side aperture (30) for receiving a tissue mass, a cutter assembly (50) comprising a hollow cutter tube having a distal end portion and a proximal end portion, the cutter tube being sized to be slidably received

within and extend axially through the introducer sheath, and the distal end portion of the cutter tube including at least one cutting edge (52); an endoscope assembly (38) including a fiber optic bundle, the bundle being sized to be received within and extend axially through the cutter tube adjacent the side aperture; and the cutter tube and the introducer sheath cooperating to sever the tissue sample by relative movement therebetween (Col. 5, lines 45 – 49). However, Clement fails to disclose the fiber optic bundle for viewing the biopsy site. Ryan et al. disclose a biopsy device for the collection of a tissue sample wherein a fiber optic is positioned adjacent the side aperture (Col. 6, lines 14 – 21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fiber optic bundle as disclosed by Clement to include means to transmit an image of the surgical site to a user in order to allow a user to visualize the site during the procedure.

8. Claims 1, 10, 23 and 32, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,505,210 to Clement in view of U.S. Patent No. 6,139,508 to Simpson et al.

In regard to claims 1, 10 23 and 32, Clement discloses a biopsy device (Figure 7) suitable for collection of a tissue sample from a biopsy site in a body lumen, the biopsy device comprising: an introducer assembly (320), a cutter assembly (334) slidably received within the introducer assembly, and a medical instrument (356) situated within the cutter assembly; the introducer assembly comprising a tubular sheath having a distal end portion that defines a side aperture (330) for receiving the tissue sample; the cutter assembly comprising a hollow cylindrical cutter having a distal end portion, the cutter being co-axial with the introducer sheath and having a lesser outside diameter than the introducer sheath inside diameter, the cylindrical cutter including at least one cutting edge (342); the medical instrument is co-axial with the hollow cutter and having a lesser outside diameter than the cutter inside diameter, and at least the introducer distal end portion and the cutter distal end portion being mounted for movement relative to one another, the relative movement of the cutter

distal end portion and the distal end portion of the tubular sheath causing the cutting of the tissue sample received therebetween. Clement fails to disclose the medical instrument being a fiber optic bundle. However, Simpson et al. disclose a biopsy device having a lumen for receiving any desired medical instrument. Simpson et al. teach a fiber optic bundle being slidably received within the lumen (Col. 12, lines 41 – 46). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the medical instrument as disclosed by Clement with a fiber optic bundle as taught by Simpson et al. in order to illuminate and visualize the working site (Col. 12, lines 41 – 43).

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMLF



Handwritten signature of JMLF, appearing to read "JMLF".

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